

REMARKS

Applicant thanks the Examiner for taking the time on September 6, 2002, to discuss the office action, mailed on July 16, 2002, and the proposed amendments to claim 25. As discussed, Applicant has modified the preamble of claims 25 and 40 to describe "a method for monitoring the amplification of a nucleic acid sequence."

Priority

The examiner has rejected the Applicant's claim of priority to U.S. Application 08/250,951, filed May 27, 1994, now U.S. Patent No. 5,532,129, for allegedly not containing support to a method of monitoring the amplification of nucleic acids. As discussed in the telephone interview on September 6, 2002, Applicant has modified the preamble of claims 25 and 40 to describe "a method for monitoring the amplification of a nucleic acid sequence." Accordingly, Applicant respectfully requests withdrawal of the rejection and reinstatement of the claim of priority to U.S. Application No. 08/250,951.

Support for independent claim 1 can be found in the specification at, e.g., FIGS. 1-2 and accompanying text; Col. 17, line 48-Col. 18, line 4, Col. 21, lines 33-Col. 22, lines 21. In particular, the step of "providing a target nucleic acid sequence" can be found at, e.g., FIGS. 1-2 and accompanying text and Col. 17, lines 48-62. Support for the step of "providing a first polynucleotide sequence having at least one donor chromophore ..." can be found, e.g., in FIGS. 1-2 and accompanying text; Col. 17, lines 48-62; and Col. 21, lines 33-41. Support for the step of "providing a second polynucleotide having at least one acceptor chromophore ..." can be found at,

e.g., FIGS. 1-2 and accompanying text; Col 17, line 63-Col. 18, line 4; and Col 21, lines 42-47.

Support for the step of "performing polymerase chain reaction to amplify the target nucleic acid sequence" can be found at, e.g., Col. 21, lines 14-21. Support for the step of hybridizing the first and second polynucleotide sequences to the target nucleic acid sequence ..." can be found at, e.g., Col. 21, lines 48-57. Support for the step of "irradiating the mixture to detect hybridizations of the first and second polynucleotide sequences by fluorescence energy transfer ..." can be found at, e.g., FIGS. 1-2 and accompanying text and Col. 21, line 66-Col. 22, line 21.

Support for independent claim 16 can also be found in the specification at, e.g., the same passages cited above for the identical steps. With respect to the steps of "providing four different nucleoside triphosphates, a thermostable amplification enzyme, and two primers, ...," "denaturing the target nucleic acid sequence to form single stranded nucleic acids at an appropriate temperature," and "elongating the target polynucleotide sequence ...," support can be found at, e.g., Col. 21, lines 14-21. A person skilled in the art would recognize these as steps in the PCR process.

#### Double Patenting

Claims 1-24 were rejected under the judicially-created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 1-17 of U.S. Patent No. 6,162,603 in view of Kidwell et al. (U.S. Patent No. 5,332,659). Without conceding the propriety of the rejection, the enclosed Terminal Disclaimer should obviate the rejection for alleged obviousness-type double patenting in view of U.S. Patent No. 6,162,603.

35 U.S.C. § 103(a)

Claims 1-24 are rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Heller (U.S. Patent No. 5,849,489) in view of Kidwell et al. (U.S. Patent No. 5,332,659). In light of the above statements regarding the correct claim of priority, this rejection becomes moot since this application claims priority to U.S. Application Serial No. 08,250,951, now U.S. Patent No. 5,532,129, which is the parent application of U.S. Patent No. 5,849,489.

CONCLUSION

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with Markings to Show Changes Made."

Prompt and favorable action on the merits of the claims is earnestly solicited. Enclosed is a check for \$55.00.

Respectfully submitted,

O'MELVENY & MYERS LLP

Dated: October 16, 2002

By: John Kappos  
John Kappos  
Reg. No. 37,861  
Attorneys for Applicant

JCK/DKW/cp  
114 Pacifica, Suite 100  
Irvine, CA 92618-3315  
(949) 737-2900  
IR1:497496.1



Patent  
Attorney Docket: 612,404-387  
(Former L&L Ref: 267/242)

Version with Markings to Show Changes Made

In the Claims:

Please amend the claims as follows:

1. (Amended) A method for ~~monitoring~~ the amplification of a nucleic acid sequence, comprising the steps of:

providing a target nucleic acid sequence;

providing a first polynucleotide sequence having at least one donor chromophore, the first polynucleotide sequence being complementary to at least a portion of the target nucleic acid sequence;

providing a second polynucleotide sequence having at least one acceptor chromophore, the second polynucleotide sequence being complementary to at least a portion of the target sequence;

performing polymerase chain reaction to amplify the target nucleic acid sequence;

hybridizing the first and second polynucleotide sequences to the target nucleic acid sequence, such that when the first polynucleotide sequence and the second polynucleotide sequence are hybridized to the target nucleic acid sequence, the donor chromophore and acceptor chromophore are in an energy transfer relationship; and

irradiating the mixture to detect hybridizations of the first and second polynucleotide sequences by fluorescence energy transfer from the one or more donor chromophores of the first polynucleotide sequence to the one or more acceptor chromophores of the second polynucleotide sequence.

RECEIVED

OCT 25 2002

TECH CENTER 1600/2900

16. (Amended) A method for ~~monitoring~~ the amplification of a nucleic acid sequence, comprising the steps of:

providing a target nucleic acid sequence;

providing a first polynucleotide sequence having at least one donor chromophore, the first polynucleotide sequence being complementary to at least a portion of the target nucleic acid sequence;

providing a second polynucleotide sequence having at least one acceptor chromophore, the second polynucleotide sequence being complementary to at least a portion of the target sequence;

providing four different nucleoside triphosphates, a thermostable amplification enzyme, and two primers, wherein the primers are substantially complementary to the target polynucleotide sequence;

denaturing the target nucleic acid sequence to form single stranded nucleic acids at an appropriate temperature;

hybridizing the first and second polynucleotide sequences to the target nucleic acid sequence, such that when the first polynucleotide sequence and the second polynucleotide sequence are hybridized to the target nucleic acid sequence, the donor chromophore and acceptor chromophore are in an energy transfer relationship; and

irradiating the mixture to detect hybridizations of the first and second polynucleotide sequences by fluorescence energy transfer from the one or more donor chromophores of the first polynucleotide sequence to the one or more acceptor chromophores of the second polynucleotide sequence;

elongating of the target polynucleotide sequence under conditions that the target polynucleotide sequence is amplifiable.